AUG 4 2000

K001913

KURARAY CO., LTD.
12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
Phone : +81-6-6348-2603
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510(k) SUMMARY

1. Submitter

1) Name	KURARAY CO., LTD.
2) Address	1-12-39, Umeda, Kita-ku, Osaka 530-8611, Japan
3) Telephone	81(Japan)-6-6348-2603
4) Facsimile	81(Japan)-6-6348-2552
5) Contact person	Shinichi Sato Dental Material Department Medical Products Division
6) Date	June 18th, 2000

2. Representing (Subsidiary of KURARAY CO., LTD.)

1) Name	KURARAY AMERICA INC.
2) Address	200 Park Avenue, New York, NY 10166-3098
3) Telephone	(212)-986-2230
4) Facsimile	(212)-867-3543
5) Contact person	Koichi Kikuchi President

3. Name of Device

1) Proprietary Name	CLEARFIL ST OPAQUER
2) Classification Name	Tooth Shade resin Material (21CFR 872.3690)
3) Common/Usual Name	Dental composite resin for masking

4. Predicate devices:
   1. PHOTO CLEARFIL OPAQUER by KURARAY CO., LTD. (K925383)
   2. OPAKER by KERR DENTAL MANUFACTURING CENTER (K955337)
   3. MONOPAQUE by IVOCLAR NORTH AMERICA INC. (K990315)

5. Description for the premarket notification
   CLEARFIL ST OPAQUER is classified into the Tooth Shade Resin Material, CFR 21 Section 872.3690, because it is a device composed of materials such as bisphenol-A glycidylmethacrylate (Bis-GMA) intended to restore carious lesions or structural defects in teeth. This product is similar and substantially equivalent in design, composition and function to the similar products which are identified in the paragraph 4 of this summary; all of which are safe, effective and beneficial.

6. Statement of the intended use
   This device is used for the following indications. Each indication is same to that of similar products.

K001913

1) Masking of metal during intraoral repair of porcelain fused-to-metal crowns.
   1. PHOTO CLEARFIL OPAQUER by KURARAY CO., LTD. (K925383)

2) Masking of metal in restoration of post and core crowns.
   1. PHOTO CLEARFIL OPAQUER by KURARAY CO., LTD. (K925383)

3) Lightening of stained or discolored teeth in porcelain or composite veneer restorations.
   1. PHOTO CLEARFIL OPAQUER by KURARAY CO., LTD. (K925383)

4) Masking of pulp capping materials.
   1. PHOTO CLEARFIL OPAQUER by KURARAY CO., LTD. (K925383)

7. Statement of the technological characteristics and safety

CLEARFIL ST OPAQUER is a product just by modifying PHOTO CLEARFIL OPAQUER that is permitted to be marketed (K925383) in its color to achieve more natural restorations. Therefore CLEARFIL ST OPAQUER is substantially equivalent to those of products sold in the U.S. market in design, components and functions.

7-1 Components

CLEARFIL ST OPAQUER are available in three shades. These components are similar to those of the products in the paragraph 4 of this summary.

7-2 Performance

There is no applicable performance standard to CLEARFIL ST OPAQUER which is a composite resin for masking the color of metal or tooth structure. This product has same performance as PHOTO CLEARFIL OPAQUER (K925383), because this material is by a product just arranging in small amount of color ingredients of PHOTO CLEARFIL OPAQUER.

7-3 Chemical ingredients and safety

The chemical ingredients have been used in the following product allowed to be sold in U.S. market. The safety of this product is substantially equivalent to the predicated devices.

1. PHOTO CLEARFIL OPAQUER by KURARAY Co., Ltd. (K925383)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Mr. Koichi Kikuchi
President
Kuraray America, Incorporated
Subsidiary of Kuraray Company, Limited, OSAKA
200 Park Avenue
New York , New York 10166-3098

Re: K001913
Trade Name: Clearfil ST Opaquer
Regulatory Class: II
Product Code: EBF
Dated: June 21, 2000
Received: June 23, 2000

Dear Mr. Kikuchi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Devices Evaluation
Center for Devices and
Radiological Health

Enclosure

K001913

510(k) Number (if known): K001913

Device Name: CLEARFIL ST OPAQUER

Indications For Use

CLEARFIL ST OPAQUER is indicated for the following applications:

1) Masking of metal during intraoral repair of porcelain fused-to-metal crowns.
2) Masking of metal in restoration of post and core crowns.
3) Lightening of stained or discolored teeth in porcelain or composite veneer restorations.
4) Masking of pulp capping materials.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Part 21 CFR 801.109)

(Optional Format 1-2-96)

Susan [redacted]

ision Sign-Off)
ion of Dental, Infection Control,
General Hospital Devices
(k) Number K001913